

## **REMARKS**

These remarks are in response to the Office Action mailed November 24, 2008. In the Office Action dated April 21, 2008, the Examiner had indicated Claim 4 would be allowable if directed to the elected sequence. Applicants believed that this claim is allowable as indicated by the Examiner in the prior Action. Applicants respectfully request clarification.

Claim 1 and 2 have been amended to set forth the claims to the elected invention and to further clarify certain claim terms. No new matter is believed to have been introduced.

### **I. PRIORITY**

Applicants respectfully submit that the application is entitled to priority of April 1, 2003. The specification of Applicants' priority application discloses information sufficient to demonstrate possession of the claimed invention at least as early as April 1, 2003. One of skill in the art would recognize that Applicants had possession of the claimed sequence by reference to the genomic sequence and protein fragments in combination with the functional and physical characteristics of the disclosure of the encoded polypeptides.

### **II. OBJECTION TO THE TITLE**

Applicants have amended the Title to more accurately describe the claimed invention.

### **III. OBJECTION TO THE DRAWINGS**

Applicants have amended the Brief Description of Figure 1 to indicate the SEQ ID NOs corresponding to the sequences as set forth in Figure 1.

### **IV. OBJECTIONS TO THE SPECIFICATION**

The Examiner indicates that the specification should be carefully reviewed to insure compliance with the sequence listing rules. Applicants submit that the rules indicate a, "Nucleotide and/or amino acid sequences as used in §§ 1.821 through 1.825 are interpreted to mean an unbranched sequence of four or more amino acids

or an unbranched sequence of ten or more nucleotides." (37 CFR 1.821). The sequences at page 16 are less than 10 nucleotides in length.

**V. CLAIM OBJECTIONS**

Claims 1, 2 and 5-10 stand objected to for reciting non-elected sequences. Applicants respectfully submit that the sequence of claims 2 and 5-10 are in proper dependent format.

**VI. REJECTION UNDER 35 U.S.C. §112, SECOND PARAGRAPH**

Claims 1 and 5-10 stand rejected under 35 U.S.C. §112, second paragraph, because the term "conservative substitutions" allegedly renders the claims indefinite. Applicants respectfully traverse this rejection.

Applicants respectfully submit that the skill in the art is high. It has long been recognized that during evolution minor "conservative substitutions" have been made in a protein's sequence with physically and chemically related amino acids resulting in similar functional activity. A search of the literature recognizes such substitutions and identifies related amino acids. Furthermore, one of skill in the art can readily determine an amino acid's physio-chemical relatedness using hydrophobicity/hydrophilicity determinations and side-group size and steric hindrances.

Furthermore, the Applicants set forth exemplary conservative amino acid substitutions in the specification (e.g., paragraph [0076]). The claims must be considered in view of the teachings of the specification and the level of ordinary skill in the art. Taking both into account the claims clearly set forth the contemplated invention and the term "conservative substitution" is not vague and indefinite.

For at least the foregoing response Applicants respectfully request withdrawal of this rejection.

**VII. REJECTION UNDER 35 U.S.C. §112, FIRST PARAGRAPH**

Claims 1 and 7-10 stand rejected under 35 U.S.C. §112, first paragraph as allegedly lacking enablement for the scope of the claimed invention. Applicants respectfully traverse this rejection.

The Examiner agrees that the claims encompass both structure and function. Furthermore, the Examiner agrees that methods of mutagenesis, random mutagenesis etc. are well known. The Examiner further recognizes that methods for testing a protein for the ability to dephosphorylate RNA polymerase II are well known. (see, e.g., the Office Action at 4-5). The Examiner then indicates that in view of these well known techniques and the structure and function recited in the claims there would still be an almost infinite possibility of variants. Applicants respectfully submit that by reciting percent identity with reference to a particular sequence along with a recited function there *cannot* be an almost infinite possibility of variants, but rather a subset that can be easily screened using routine skill as indicated by the Examiner.

The Examiner then goes on to indicate, as discussed more fully below, that Cocks et al. and Meinzel et al. would be capable of modifying their defective sequence to arrive at Applicants' invention using the same techniques as described above. The Examiner takes the position that Applicants are not enabled but then goes on to indicate that Cocks et al. in view of Meinzel et al. would be enabled to (i) select one of numerous (almost infinite) polypeptides sequences from Cocks et al., (ii) identify one sequence that would have a stop codon from an almost infinite number of sequences in the correct reading frame and then (iii) insert upstream at one of almost an infinite number of points a starting methionine. The Examiner appears to indicate that Applicants are not entitled to adding or substituting amino acids having a defined structure and function using routine skill in the art, but Cocks et al. in view of Meinzel et al. are entitled to random selection of an infinite number of polypeptides to arrive at Applicants' claimed invention having structure but which is not functionally defined to be a kinase. In such instance Cocks et al. and Meinzel et al. cannot be enabling references as discussed below. In other words the Examiner "enables" Cocks et al. and Meinzel et al. yet alleges that Applicants' invention is not enabled.

Applicants respectfully request withdrawal of the present rejection.

**VIII. REJECTION UNDER 35 U.S.C. §102**

Claims 1 and 5-10 stand rejected under §102 as allegedly anticipated by Venter et al. (2002). Applicants respectfully traverse this rejection.

Venter et al. do not teach Applicants' invention. Venter et al. do not teach or suggest a polypeptide having the recited activity as set forth in Applicants' claims. Venter et al. do not teach or suggest a polynucleotide that encodes a polypeptide of SEQ ID NO:2.

Furthermore, as the Federal Circuit stated in *In Re Fisher* (Fed. Cir. 2005) a gene sequence without a specific function lacks a specific and substantial utility and the application in question therefore also does not meet the enablement requirement of 35 U.S.C. § 112, as it incorporates the utility requirement of 35 U.S.C. § 101. Accordingly, Applicants submit that Venter et al. lacks enablement for a kinase as set forth by Applicants' claimed invention. A non-enabling disclosure is not prior art.

Venter et al. do not teach or suggest each and every element of Applicants' claimed invention. According, Applicants respectfully request withdrawal of the rejection.

**VII. REJECTION UNDER 35 U.S.C. §103**

Claims 1, 3 and 5-10 stands rejected under 35 U.S.C. §103 as allegedly unpatentably over Cocks et al. (2003) in view of Meinnel et al. (1993). Applicants respectfully traverse this rejection.

The Cocks et al. patent is a listing of putative sequence that may or may not have activity, that may or may not have start codons and may or may not have stop codons. SEQ ID NO:843, which is relied upon for the present rejection is a sequence of nearly 2000 basepairs of which only half appear to align. Applicants submit that there is no teaching or suggestion in Cocks et al. that identify a sequence set forth by Applicants having the biological activity as set forth in the claims. Cocks et al. fail to teach and suggest each and every element of Applicants' claimed invention (e.g., Cocks et al. fails to teach the actual sequence and the biological activity encoded by the claimed polynucleotide).

In order to overcome the deficiencies of Cocks et al., the Office Action combines Meinnel et al. for the teaching that nearly all proteins begin with an N-

terminal Methionine. Furthermore, Meinzel et al. indicates that "most" have such a methionine, clearly some do not.

As stated above, the Cocks et al. disclosure is a non-enabling disclosure for at least two reasons. First, a sequence lacking a functional utility lacks enablement (see, e.g., *In re Fisher* (Fed. Cir. 2005)). Second, the Examiner attributes enablement only to the extent that a proper start codon is inserted in any number of infinitely possible positions upstream of the sequence identified in Cocks et al. For Cocks et al. and Meinzel et al. to be enabling would require modification of their defective sequence to arrive at Applicants' invention. For Cocks et al. in view of Meinzel et al. to be enabled one would have to (i) select one of numerous (almost infinite) polypeptide sequences from Cocks et al., (ii) identify one sequence that would have a stop codon from an almost infinite number of sequences in the correct reading frame and then (iii) insert upstream at one of almost an infinite number of points a starting methionine. Even with these feats, the reference would still fail to describe a kinase. The Examiner appears to indicate that Applicants are not entitled to adding or substituting amino acids having a defined structure and function using routine skill in the art, but Cocks et al. in view of Meinzel et al. are entitled to random selection of an infinite number of polypeptides to arrive at Applicants' claimed invention having structure but which is not functionally defined to be a kinase. Cocks et al. in view of Meinzel et al. would lack enablement for at least the same reasons that the Examiner indicates for Applicants' invention. In such instance Cocks et al. and Meinzel et al. cannot be enabling references as discussed below. Thus, the combination of Cocks et al. and Meinzel et al. are not enabling and thus cannot be prior art.

Meinzel et al. is a general reference that does little to overcome the lack of enablement or description by Cocks et al. Rather, Meinzel et al. teach only that start codons are important but does not provide any indication to one of skill in the art a reasonable expectation of any success in generating Applicants' claimed invention based upon the disclosure of Cocks et al.

For, at least, the foregoing reasons the claims submitted herewith are non-obvious over the references either alone or in combination.

For at least the foregoing, the Applicant submits that the claimed invention is patentable and request reconsideration and notice of such allowable subject matter.

The Director is authorized to charge any required fee or credit any overpayment to Deposit Account Number 50-4586, please reference the attorney docket number above.

The Examiner is invited to contact the undersigned at the below-listed telephone number, if it is believed that prosecution of this application may be assisted thereby.

Respectfully submitted,

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